Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1093121	04/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Millennium Medical Management Llc	7955 Spyglass Hill Rd Ste A, Melbourne, FL	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An initial certification survey was conducted on April 28, 2022. Millennium Medical Management LLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review, and interview, the laboratory failed to document the initial competency assessment for one of one Technical Consultant from 12/13/2021 to 04/28/2022. Findings: Review of the Laboratory Personnel Report dated and signed by the Laboratory Director on 04/27/2020 showed there was one Technical Consultant. Review of personnel records revealed there was no initial competency evaluations for the Technical Consultant. On 04/28/2022 at 9:40 AM, Testing Personnel A stated there was no competency evaluation for the Technical Consultant.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain documentation on the verification of performance specifications for the Complete Blood Count testing on the Horiba Micro 60 hematology analyzer from 12/13/2021 to 04/28/2022. Findings: Review of the laboratory's records for performance verification (validation) for the hematology analyzer showed the laboratory failed to maintain documentation of the accuracy, reportable range, and the manufacturer's normal ranges appropriate for their patient population. On 04/28/20/22 at 10:11 AM, Testing Personnel A explained the field technician that performed the validation did not leave a copy of all the paperwork from the validation.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to document corrective actions when the refrigerator temperatures were not within the acceptable temperature range of 2 to 8 degrees Celsius (C) from 12/13/2021 to 03/27/2022. Findings: On 4/28/2022 at 9:20 AM, the Horiba Medical Minotrol 16 Whole Blood Hematology Controls were observed in the laboratory refrigerator. The hematology controls box noted to store the controls at "2 - 8 degrees C." Review of the "Laboratory Temperature Log" showed the temperatures were out of range for the following dates: 12/13/2021 temperature 1.8 degrees C 12/17/2021 temperature 1.8 degrees C 12/21/2021 temperature 1.9 degrees C 12/22/2021 temperature 1.9 degrees C 01/03/2022 temperature 1.9 degrees C 01/04/2022 temperature 1.9 degrees C 01/13/2022 temperature 1.9 degrees C 01/26/2022 temperature -1.2 degrees C 01/27/2022 temperature 0.0 degrees C 01/28/2022 temperature -0.6 degrees C 02/03/2022 temperature 0.9 degrees C 02/04/2022 temperature 0.4 degrees C 02/07/2022 temperature 0.6 degrees C 02/08/2022 temperature -0.9 degrees C 02/09/2022 temperature -0.4 degrees C 02/10/2022 temperature 0.2 degrees C 02/11/2022 temperature 1.6 degrees C 02/14/2022 temperature 1,6 degrees C 02/16/2022 temperature 0.0 degrees C 02/17/2022 temperature 0.7 degrees C 02/18/2022 temperature 0.2 degrees C 02/21/2022 temperature 0.8 degrees C 02/22/2022 temperature 0.4 degrees C 02/24/2022 temperature 1.8 degrees C 03/01/2022 temperature 1.8 degrees C 03/03/2022 temperature 1.5 degrees C 03/04/2022 temperature 1.5 degrees C 03/05/2022 temperature 1.8 degrees C 03/08/2022 temperature 1.7 degrees C 03/09/2022 temperature 1.5 degrees C 03/10/2022 temperature 0.1 degrees C 03/11/2022 temperature 1.1 degrees C 03/12/2022 temperature 1.6 degrees C 03/14/2022 temperature 0.2 degrees C 03/15/2022 temperature 0.0 degrees C 03/19/2022 temperature 1.2 degrees C 03/22/2022

	temperature 1.8 degrees C 03/24/2022 temperature -0.2 degrees C 03/26/2022 temperature 0.8 degrees C 03/27/2022 temperature 1.1 degrees C On 04/28/2022 at 11: 45 AM, Testing Personnel A stated there was no corrective action documented for the temperatures that were out of range.